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(54) ENDOVASCULAR ELECTROLYTICALLY DETACHABLE GUIDEWIRE TIP

ENDOVASKULÄRE ELEKTROLYTISCH ABTRENNBARE FÜHRUNGSDRAHTSPITZE

EXTREMITE DE FIL DE GUIDAGE ENDOVASCULAIRE DETACHABLE DE MANIERE ELECTROLYTIQUE

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Description

[0001] The invention relates to an apparatus for endovascular electrothrombic formation of thrombi in arteries, veins, aneurysms, vascular malformations and arteriovenous fistulas.

[0002] Approximately 25,000 intracranial aneurysms rupture every year in North America. The primary purpose of treatment for ruptured intracranial aneurysm is to prevent rebleeding. At the present time, three general methods of treatment exist, namely an extravascular, endovascular and extra-endovascular approach.

[0003] The extravascular approach is comprised of surgery or microsurgery of the aneurysm or treatment site for the purpose of preserving the parent artery. This treatment is common with intracranial berry aneurysms. The methodology comprises the step of clipping the neck of the aneurysm, performing a suture-ligation of the neck, or wrapping the entire aneurysm. Each of these surgical procedures is performed by intrusive invasion into the body and performed from outside the aneurysm or target site. General anesthesia, craniotomy, brain retraction and arachnoid dissection around the neck of the aneurysm and placement of a clip are typically required in these surgical procedures. Surgical treatment of vascular intracranial aneurysm can expect a mortality rate of 4-8% with a morbidity rate of 18-20%. Because of the mortality and morbidity rate expected, the surgical procedure is often delayed while waiting for the best surgical time with the result that an additional percentage of patients will die from the underlying disease or defect prior to surgery. For this reason the prior art has sought alternative means of treatment.

[0004] In the endovascular approach, the interior of the aneurysm is entered through the use of a microcatheter. Recently developed microcatheters, such as those shown by **Engleson**, "Catheter Guidewire", U.S. Patent 4,884,579 and as described in **Engleson**, "Catheter for Guidewire Tracking", U.S. Patent 4,739,768 (1988), allow navigation into the cerebral arteries and entry into a cranial aneurysm.

[0005] In such procedures a balloon is typically attached to the end of the microcatheter and it is possible to introduce the balloon into the aneurysm, inflate it, and detach it, leaving it to occlude the sac and neck with preservation of the parent artery. While endovascular balloon embolization of berry aneurysms is an attractive method in situations where an extravascular surgical approach is difficult, inflation of a balloon into the aneurysm carries some risk of aneurysm rupture due to possible over-distention of portions of the sac and due to the traction produced while detaching the balloon.

[0006] While remedial procedures exist for treating a ruptured aneurysm during classical extravascular surgery, no satisfactory methodology exists if the aneurysm breaks during an endovascular balloon embolization.

[0007] Furthermore, an ideal embolizing agent should adapt itself to the irregular shape of the internal walls of the aneurysm. On the contrary, in a balloon embolization the aneurysmal wall must conform to the shape of the balloon. This may not lead to a satisfactory result and further increases the risk of rupture.

[0008] Still further, balloon embolization is not always possible. If the diameter of the deflated balloon is too great to enter the intracerebral arteries, especially in the cases where there is a vasospasm, complications with ruptured intracranial aneurysms may occur. The procedure then must be deferred until the spasm is resolved and this then incurs a risk of rebleeding.

[0009] In the extra-intravascular approach, an aneurysm is surgically exposed or stereotaxically reached with a probe. The wall of the aneurysm is then perforated from the outside and various techniques are used to occlude the interior in order to prevent it from rebleeding. These prior art techniques include electrothrombosis, isobutyl-cyanoacrylate embolization, hog-hair embolization and ferromagnetic thrombosis.

[0010] In the use of electrothrombosis for extra-intravascular treatment the tip of a positively charged electrode is inserted surgically into the interior of the aneurysm. An application of the positive charge attracts white blood cells, red blood cells, platelets and fibrinogen which are typically negatively charged at the normal pH of the blood. The thrombic mass is then formed in the aneurysm about the tip. Thereafter, the tip is removed. See **Mullan**, "Experiences with Surgical Thrombosis of Intracranial Berry Aneurysms and Carotid Cavernous Fistulas", J. Neurosurg., Vol. 41, December 1974; **Hosobuchi**, "Electrothrombosis Carotid-Cavernous Fistula", J. Neurosurg., Vol. 42, January 1975; **Araki et al.**, "Electrically Induced Thrombosis for the Treatment of Intracranial Aneurysms and Angiomas", Excerpta Medica International Congress Series, Amsterdam 1965, Vol. 110, 651-654; **Sawyer et al.**, "Bio-Electric Phenomena as an Etiological Factor in Intravascular Thrombosis", Am. J. Physiol., Vol. 175, 103-107 (1953); **J. Piton et al.**, "Selective Vascular Thrombosis Induced by a Direct Electrical Current; Animal Experiments", J. Neuroradiology, Vol. 5, pages 139-152 (1978). However, each of these techniques involves some type of intrusive procedure to approach the aneurysm from the exterior of the body.

[0011] The prior art has also devised the use of a liquid adhesive, isobutyl-cyanoacrylate (IBCA) which polymerizes rapidly on contact with blood to form a firm mass. The liquid adhesive is injected into the aneurysm by puncturing the sac with a small needle. In order to avoid spillage into the parent artery during IBCA injection, blood flow through the parent artery must be momentarily reduced or interrupted. Alternatively, an inflated balloon may be placed in the artery at the level of the neck of the aneurysm for injection. In addition to the risks caused by temporary blockage of the parent artery, the risks of seepage of such a polymerizing adhesive into the parent artery exists, if it is not com-

pletely blocked with consequent occlusion of the artery.

[0012] Still further, the prior art has utilized an air gun to inject hog hair through the aneurysm wall to induce internal thrombosis. The success of this procedure involves exposing the aneurysm sufficiently to allow air gun injection and has not been convincingly shown as successful for thrombic formations.

[0013] Ferromagnetic thrombosis in the prior art in extraintravascular treatments comprises the stereotactic placement of a magnetic probe against the sac of the aneurysm followed by injection into the aneurysm by an injecting needle of iron microspheres. Aggregation of the microspheres through the extravascular magnet is followed by interneuysmatic thrombus. This treatment has not been entirely successful because of the risk of fragmentation of the metallic thrombus when the extravascular magnet is removed. Suspension of the iron powder in methyl methymethacrylate has been used to prevent fragmentation. The treatment has not been favored, because of the need to puncture the aneurysm, the risk of occlusion of the parent artery, the use of unusual and expensive equipment, the need for a craniectomy and general anesthesia, and the necessity to penetrate cerebral tissue to reach the aneurysm.

[0014] Endovascular coagulation of blood is also well known in the art and a device using laser optically generated heat is shown by **O'Reilly**, "Optical Fiber with Attachable Metallic Tip for Intravascular laser Coagulation of Arteries, Veins, Aneurysms, Vascular Malformation and Arteriovenous Fistulas", U.S. Patent 4,735,201 (1988). See also, **O'Reilly** et al., "Laser Induced Thermal Occlusion of Berry Aneurysms: Initial Experimental Results", Radiology, Vol. 171, No. 2, pages 471-74 (1989). O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter. The tip is adhesively bonded to a optic fiber disposed through the microcatheter. Optical energy is transmitted along the optic fiber from a remote laser at the proximal end of the microcatheter. The optical energy heats the tip to cauterize the tissue surrounding the neck of the aneurysm or other vascular opening to be occluded. The catheter is provided with a balloon located on or adjacent to its distal end to cut off blood flow to the site to be cauterized and occluded. Normally, the blood flow would carry away the heat at the catheter tip, thereby preventing cauterization. The heat in the tip also serves to melt the adhesive used to secure the tip to the distal end of the optical fiber. If all goes well, the tip can be separated from the optical fiber and left in place in the neck of the aneurysm, provided that the cauterization is complete at the same time as the hot melt adhesive melts.

[0015] A thrombus is not formed from the heated tip. Instead, blood tissue surrounding the tip is coagulated. Coagulation is a denaturation of protein to form a connective-like tissue similar to that which occurs when the albumen of an egg is heated and coagulates from a clear running liquid to an opaque white solid. The tissue characteristics and composition of the coagulated tissue is therefore substantially distinct from the thrombosis which is formed by the thrombotic aggregation of white and red blood cells, platelets and fibrinogen. The coagulative tissue is substantially softer than a thrombic mass and can therefore more easily be dislodged.

[0016] **O'Reilly's** device depends at least in part upon the successful cauterization timed to occur no later than the detachment of the heat tip from the optic fiber. The heated tip must also be proportionally sized to the neck of the aneurysm in order to effectively coagulate the tissue surrounding it to form a blockage at the neck. It is believed that the tissue in the interior of the aneurysm remains substantially uncoagulated. In addition, the hot melt adhesive attaching the tip to the optic fiber melts and is dispersed into the adjacent blood tissue where it resolidifies to form free particles within the intracranial blood stream with much the same disadvantages which result from fragmentation of a ferromagnetic electrothrombosis.

[0017] Therefore, what is needed is an apparatus which avoids each of the shortcomings and limitations of the prior art discussed above.

[0018] US-A-4 748 986 discloses a guidewire intended for use in guiding a catheter into small vessels in vascular systems, particularly into cardiovascular systems. The guidewire includes a main flexible elongate element formed of a high torsional strength material such as stainless steel. In one embodiment (Figures 1-3) this element includes a tapered intermediate portion and a flattened distal portion. An elongate coil, formed of a suitable material such as stainless steel, is provided concentrically on the flexible elongate element and extends substantially the entire length thereof from the proximal end to the distal end of the tapered portion. A TEFLON coating is provided on the coil to enhance its lubricity. A further coil is provided adjoining the stainless steel coil and extending distally therefrom. This further coil is formed of a material which is substantially radiopaque, such as platinum. The distal end of the stainless steel coil and the proximal extremity of the platinum coil are threaded together and brazed to the distal tip of the tapered portion of the elongate element. The flattened distal portion of the elongate element extends longitudinally inside the platinum coil. A tungsten safety ribbon also extends from the brazed connection to a rounded gold protrusion provided at the distal extremity of the platinum coil.

[0019] According to the present invention there is provided a combination of a guidewire and a voltage source, the guidewire being connected to the voltage source and being for use with a microcatheter in endovascular electrothrombosis, the guidewire comprising:

a core wire having a main body and a distal portion; and

a tip portion for endovascular insertion within a vascular cavity, said tip portion being coupled to said

main body via said distal portion and comprised of material not susceptible to electrolytic disintegration in blood;

wherein said distal portion is susceptible to electrolytic disintegration in blood whereby, on the application of current to the guidewire by the voltage source when said tip portion is disposed in the vascular cavity, endovascular electrothrombosis can be performed and at least one portion of said distal portion electrolytically disintegrated to detach said tip portion from said main body.

[0020] Preferably the distal portion comprises an exposed stainless steel coil connected at its proximal end to the core wire and connected at its distal end to the tip portion. The distal portion may further comprise a threadlike extension of the main body of the core wire extending concentrically within the stainless steel coil and connected at its distal end to the connection of the distal end of the stainless steel coil and the tip portion. In this case, both the threadlike extension and the stainless steel coil need to be electrolytically disintegrated at least at one point in order to detach the tip portion from the main body. Alternatively, the threadlike extension may be omitted so that the stainless steel coil defines an interior space that is free and unreinforced.

[0021] In some embodiments the tip portion is a platinum coil.

[0022] The tip portion advantageously may be a long and pliable segment having a length sufficient to substantially fill the vascular cavity when disposed therein.

[0023] The long and pliable segment may not be prebiased. Alternatively, it may be prebiased to form a helix or spiral when advanced from a microcatheter into the vascular cavity. It may be prebiased to have a conical envelope or to have a cylindrical envelope.

[0024] Embodiments of guidewires in accordance with the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a partially cross-sectioned side view of a first embodiment of guidewire in accordance with the present invention;

Figure 1A is an enlargement of the distal end of the guidewire of Figure 1;

Figure 2 is a partially cross-sectioned side view of a second embodiment of a guidewire in accordance with the present invention;

Figure 2A is an enlargement of the distal end of the guidewire of Figure 2;

Figure 3 is an enlarged side view of a third embodiment of a guidewire in accordance with the present invention, with a microcatheter portion cut away in longitudinal cross-sectional view;

Figure 4 is a simplified depiction of the guidewire of Figure 3 shown disposed within a simple cranial aneurysm; and

Figure 5 is a depiction of the guidewire of Figure 4 shown after electrolytic detachment of its detachable coil.

[0025] An artery, vein, aneurysm, vascular malformation or arterial fistula is occluded through endovascular electrothrombosis by the endovascular insertion of a platinum guidewire tip into the vascular cavity followed by application of a positive current. The guidewire tip is then separated from the guidewire by electrolytic separation of the tip from the guidewire. A portion of the guidewire connected between the tip and the body of the guidewire is comprised of stainless steel and exposed to the bloodstream so that upon continued application of a positive current to the exposed portion, the exposed portion is corroded away at least at one location and the tip is separated from the body of the guidewire. The guidewire and the microcatheter are thereafter removed leaving the guidewire tip embedded in the thrombus formed within the vascular cavity.

[0026] In Figure 1 a conventional Teflon (registered trade mark) laminated or similarly insulated stainless steel guidewire 10 is disposed within a protective microcatheter (not shown). Stainless steel guidewire 10 is approximately 0.254-0.508 mm in diameter. In the illustrated embodiment, guidewire 10 is tapered at its distal end to form a conical section 12 which joins a section 14 of reduced diameter which extends longitudinally along a length 16 of guidewire 10. Section 16 then narrows gradually down to a thin threadlike portion 18 beginning at a first bonding location 20 and ending at a second bonding location 22.

[0027] The stainless steel guidewire 10, comprised of that portion disposed within the microcatheter body, tapered section 12, reduced diameter section 16 and threadlike section 18, is collectively referred to as a core wire which typically is 50 - 300 cm. in length.

[0028] In the illustrated embodiment the portion of the core wire extending from tapered section 12 to second bonding location 22 is collectively referred to as the grinding length and may typically be between 20 and 50 cm. in length.

[0029] Reduced diameter portion 14 and at least part of sections 12 and first bonding location 20 may be covered with an insulating Teflon laminate 24 which encapsulizes the underlying portion of guidewire 10 to prevent contact with the blood.

[0030] A stainless steel coil 26 is soldered to the proximate end of threadlike portion 18 of guidewire 10 at first bonding location 20. Stainless steel coil 26 is typically 3 to 10 cm. in length and like guidewire 10 has a diameter typically between 0.254-0.508 mm.

[0031] The distal end of stainless steel coil 26 is soldered to the distal end of threadlike portion 18 of guidewire 10 and to the proximal end of a platinum secondary coil 28 at second bonding location 22. Secondary coil 28 itself forms a spiral or helix typically between 2 to 10 mm. in diameter. The helical envelope formed by

secondary coil 28 may be cylindrical or conical. Like guidewire 10 and stainless steel coil 26, secondary coil 28 is between approximately 0.254-0.508 mm in diameter. The diameter of the wire itself forming stainless steel coil 26 and coil 28 is approximately between 0.025 - 0.127 mm (0.001 - 0.005 inch).

[0032] The distal end of secondary coil 28 is provided with a platinum soldered tip 30 to form a rounded and smooth termination to avoid puncturing the aneurysm or tearing tissue.

[0033] Although prebiased to form a cylindrical or conical envelope, secondary coil 28 is extremely soft and its overall shape is easily deformed. When inserted within the microcatheter (not shown), secondary coil 28 is easily straightened to lie axially within the microcatheter. Once disposed out of the tip of the microcatheter, secondary coil 28 forms the shape shown in Figure 1 and may similarly be loosely deformed to the interior shape of the aneurysm.

[0034] As will be described below in greater detail in connection with the third embodiment of Figure 3, after placement of secondary coil 28 within the interior of the aneurysm, a direct current is applied to guidewire 10 from a voltage source exterior to the body. The positive charge on secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis. Detachment of the tip occurs either: (1) by continued application of current for a predetermined time when the portion 18 is exposed to blood; or (2) by movement of the wire to expose portion 18 to blood followed by continued current application for a predeteremined time. Ultimately, both threadlike portion and stainless steel coil 26 will be completely disintegrated at least at one point, thereby allowing guidewire 10 to be withdrawn from the vascular space while leaving secondary coil 28 embedded within the thrombus formed within the aneurysm.

[0035] Figure 2 illustrates in enlarged partially cross-sectional view a second embodiment of the invention. Stainless steel core 32 terminates in a conical distal portion 34. Stainless steel coil 36, shown in cross-sectional view, is soldered to distal portion 34 of guidewire 32 at bonding location 38. The opposing end of the stainless steel coil 36 is provided with a soldered, rounded platinum tip 40. In the illustrated embodiment, stainless steel core wire 32 is approximately 0.010 inch in diameter with the length of stainless steel coil 36 being approximately 8 cm. with the longitudinal length of platinum tip 40 being between 3 and 10 mm. The total length of guidewire 32 from tip 40 to the proximate end is approximately 150 cm.

[0036] The embodiment of Figure 2 is utilized in exactly the same manner as described above in connection with Figure 1 to form a thrombic mass within an aneurysm or other vascular cavity. The embodiment of Figure 2 is distinguished from that shown in Figure 1 by the absence of the extension of stainless core 32 through coil 36 to tip 40. In the case of the embodiment of Figure 2 no inner core or reinforcement is provided within stainless steel coil 36. Threadlike portion 18 is provided in the embodiment of Figure 1 to allow increased tensile strength of the guidewire. However, a degree of flexibility of the guidewire is sacrificed by the inclusion even of threadlike tip 18, so that the embodiment of Figure 2 provides a more flexible tip, at least for that portion of the microguidewire constituting the stainless steel coil 36.

[0037] It is expressly understood that the helical secondary coil tip of the embodiment of Figure 1 could similarly be attached to stainless steel coil 36 of the embodiment of Figure 2 without departing from the scope of the invention.

[0038] Thinned and threadlike portion guidewires disposed concentrically within coiled portions are well known and are shown in **Antoshkiw**, "Disposable Guidewire", U.S. Patent 3,789,841 (1974); **Sepetka** et al., "Guidewire Device", U.S. Patent 4,832,047 (1989); **Engleson**, "Catheter Guidewire", U.S. Patent 4,884,579 (1989); Samson et al., "Guidewire for Catheters", U.S. Patent 4,538,622 (1985); and **Samson** et al., "Catheter Guidewire with Short Spring Tip and Method of Using the Same", U.S. Patent 4,554,929 (1985).

[0039] Turn now to the third embodiment of the invention as shown in Figure 3. Figure 3 shows an enlarged side view of a guidewire, generally denoted by reference numeral 42, disposed within a microcatheter 44 shown in cross-sectional view. Like the embodiment of Figure 1, a stainless steel coil 46 is soldered to a conical portion 48 of guidewire 22 at a first bonding location 50. A thin threadlike extension 52 is then longitudinally disposed within stainless steel coil 46 to a second bonding location 54 where stainless steel coil 46 and threadlike portion 52 are soldered to a soft platinum coil 56. Platinum coil 56 is not prebiased, nor does it contain any internal reinforcement, but is a free and open coil similar in that respect to stainless steel coil 36 of the embodiment of Figure 2.

[0040] However, platinum coil 56 is particularly distinguished by its length of approximately 1 to 50 cm. and by its flexibility. The platinum or platinum alloy used is particularly pliable and the diameter of the wire used to form platinum coil 56 is approximately 0.025 - 0.127 mm (0.001 - 0.005 inch) in diameter. The distal end of platinum coil 56 is provided with a smooth and rounded platinum tip 58 similar in that respect to tips 30 and 40 of Figures 1 and 2, respectively.

[0041] When coil 56 is disposed within microcatheter 44, it lies along the longitudinal lumen 60 defined by microcatheter 44. The distal end 62 of microcatheter 60 as then placed into the neck of the aneurysm and the guidewire 42 is advanced, thereby feeding tip 58 and platinum coil 56 into aneurysm 64 until bonding location 50 resides in the neck of the aneurysm as best depicted in the diagrammatic cross-sectional view of Figure 4.

[0042] Figure 4 illustrates the insertion of the embodiment of Figure 3 within a vessel 66 with distal tip of

microcatheter 44 positioned near neck 68 of aneurysm 64. Coil 56 is fed into aneurysm 64 until at least a portion of stainless steel coil 46 is exposed beyond the distal tip 62 of microcatheter 44. A positive electric current of approximately 0.01 to 2 milliamps at 0.1 - 6 volts is applied to guidewire 42 to form the thrombus. Typically a thrombus will form within three to five minutes. The negative pole 72 of voltage source 70 is typically placed over and in contact with the skin.

[0043] After the thrombus has been formed and the aneurysm completely occluded, tip 58 and coil 56 are detached from guidewire 42 by electrolytic disintegration of at least one portion of stainless steel coil 46. In the illustrated embodiment this is accomplished by continued application of current until the total time of current application is almost approximately four minutes.

[0044] At least one portion of stainless steel coil 46 will be completely dissolved through by electrolytic action within 3 to 10 minutes, usually about 4 minutes. After separation by electrolytic disintegration, guidewire 42, microcatheter 44 and the remaining portion of coil 46 still attached to guidewire 42 are removed from vessel 66, leaving aneurysm 64 completely occluded as diagrammatically depicted in Figure 5 by thrombus 74. It will be appreciated that the time of disintegration may be varied by altering the dimensions of the portions of the wire and/or the current.

[0045] The process is practiced under fluoroscopic control with local anesthesia at the groin. A transfemoral microcatheter is utilized to treat the cerebral aneurysm. The platinum is not affected by electrolysis and the remaining portions of the microcatheter are insulated either by a Teflon lamination directly on guidewire 42 and/or by microcatheter 44. Only the exposed portion of the guidewire 46 is affected by the electrolysis.

[0046] It has further been discovered that thrombus 74 continues to form even after detachment from guidewire 42. It is believed that a positive charge is retained on or near coil 56 which therefore continues to attract platelets, white blood cells, red blood cells and fibrinogen within aneurysm 64.

[0047] Many alterations and modifications may be made by those having ordinary skill in the art. Therefore, it must be understood that the shape of the tip or distal platinum coil used in combination with the guidewire according to the invention may be provided with a variety of shapes and envelopes. Still further, the diameter of the guidewire, various of the guidewire described above and the stainless steel coil immediately proximal to the detachable tip may be provided with differing diameters or cross sections to vary the times and current magnitudes necessary in order to effectuate electrolytic detachment from the tip. Still further, the invention may include conventional electronics connected to the proximal end of the guidewire for determining the exact instant of detachment of the distal tip from the guidewire.

[0048] Therefore, the illustrated embodiments have been set forth only for the purposes of clarity and example and should not be taken as limiting the invention as defined by the following claims.

[0049] The following is a non-limitative summary of the preferred methods of use of the illustrated embodiments of guidewires.

[0050] The above described embodiments of guidewires may be used to form a thrombus within a vascular cavity by first endovascularly disposing the guidewire, near an endovascular opening into the vascular cavity. The distal tip of the guidewire is then disposed into the vascular cavity. An electrical signal is applied to the distal tip within the vascular cavity to form a thrombus within the vascular cavity about the distal tip. The distal tip is detached from the main body of the guidewire to leave the distal tip within the vascular cavity and the thrombus electrically formed within the vascular cavity.

[0051] As a result, electrical formation of a thrombus is completely endovascularly formed.

[0052] The step of disposing the distal tip in the vascular cavity further comprises the step of substantially occupying the vascular cavity with the distal tip.

[0053] In one embodiment the step of substantially occupying the vascular cavity comprises the step of filling the vascular cavity with a long and pliable length of the distal tip.

[0054] The step of detaching the distal tip from the main body of the guidewire comprises the step of electrolytically detaching the distal tip.

[0055] The step of electrolytically detaching the distal tip from the main body of the guidewire comprises the step of electrolytically disintegrating at less one portion of a connecting segment extending between the main body of the guidewire and the distal tip.

[0056] The step of electrolytically disintegrating the connecting segment comprises the step of electrolytically corroding away at least a portion of a coil segment.

[0057] The step of electrolytically corroding the coil segment comprises the step of electrolytically disintegrating a stainless steel coil segment.

[0058] The step of applying an electrical signal to the distal tip to form the thrombus comprises the step of applying a positive direct current for a first predetermined time period. The tip can be detached in at least three different ways. First, the same current for forming the thrombosis may also simultaneously be used to detach the tip. Second, the current, which forms the thrombosis or initiates the continuing formation of the thrombosis during a following period of no current, is followed by a current of the same or different magnitude during a second time period to effect detachment. Third, the thrombosis is formed during a time period during which the disintegratable distal portion of the core wire is arranged and configured not to be exposed to the blood. The guidewire is then repositioned so the disintegratable portion is exposed to electrolytic disintegration in the blood by application of the same or different level

of current for an additional time period to effect detachment.

Claims

1. A combination of a guidewire (10,42) and a voltage source (70), the guidewire (10,42) being connected to the voltage source (70) and being for use with a microcatheter (44) in endovascular electrothrombosis, the guidewire (10,42) comprising:

   a core wire having a main body (12,16;32) and a distal portion (18,26,36,46); and
   a tip portion (28,56) for endovascular insertion within a vascular cavity, said tip portion being coupled to said main body (12,16,32) via said distal portion (18,26,36,46) and comprised of material not susceptible to electrolytic disintegration in blood;
   wherein said distal portion (18,26,36,46) is susceptible to electrolytic disintegration in blood whereby, on the application of current to the guidewire (10,42) by the voltage source when said tip portion (28,56) is disposed in the vascular cavity, endovascular electrothrombosis can be performed and at least one portion of said distal portion (18,26,36,46) electrolytically disintegrated to detach said tip portion (28,56) from said main body (12,16,32).

2. A combination as claimed in claim 1, wherein said distal portion (18,26,36,46) comprises an exposed stainless steel segment.

3. A combination as claimed in claim 2, wherein said stainless steel segment comprises a stainless steel coil (26,36,46) connected at its proximal end to said core wire and connected at its distal end to said tip portion (28,56).

4. A combination as claimed in claim 3, wherein said stainless steel segment further comprises a threadlike extension (18,52) of the main body (12,16) of the core wire extending concentrically within said stainless steel coil (26,46) and connected at its distal end to the connection of the distal end of the stainless steel coil (26,46) and the tip portion (28,56), both said threadlike extension (18,52) and said stainless steel coil (26,46) being susceptible to electrolytic disintegration at least at one point in order to detach the tip portion (28,56) from the main body (12,16).

5. A combination as claimed in claim 3, wherein said stainless steel coil (36) defines an interior space, said interior space being free and unreinforced.

6. A combination as claimed in claim 3 or claim 4, wherein the stainless steel coil (26) is between 3 and 10 cm in length and has a diameter between 0.254 mm and 0.508 mm.

7. A combination as claimed in any one of the preceding claims, wherein the tip portion (28,56) is comprised of a metal not susceptible to electrolytic disintegration in blood.

8. A combination as claimed in claim 1, wherein the tip portion (28,56) is made of platinum or platinum alloy.

9. A combination as claimed in claim 8, wherein the tip portion (28,56) is made of 479 platinum alloy.

10. A combination as claimed in any one of the preceding claims, wherein the tip portion (28,56) is a long and pliable segment.

11. A combination as claimed in any one of claims 1 to 4, wherein the tip portion (28) comprises a long and pliable segment and said segment is prebiased to form a helical or spiral coil when advanced from the microcatheter into the vascular cavity.

12. A combination as claimed in claim 11, wherein the helical or spiral coil is between 2 and 10 mm in diameter.

13. A combination as claimed in claim 11 or claim 12, wherein the helical or spiral coil is prebiased to have a conical envelope.

14. A combination as claimed in claim 11 or claim 12, wherein the helical or spiral coil is prebiased to have a cylindrical envelope.

15. A combination as claimed in any one of claims 1 to 4, wherein the tip portion (56) comprises a coil which is not prebiased.

16. A combination as claimed in claim 15, wherein the tip portion (56) has a length of approximately 1 to 50 cm.

17. A combination as claimed in any one of claims 1 to 4, wherein the tip portion (28) is comprised of a metal not susceptible to electrolytic disintegration in blood, is a long and pliable segment and comprises a coil formed by the long and pliable segment.

18. A combination as claimed in claim 17, wherein the coil has a diameter of between 0.254 and 0.508 mm.

19. A combination as claimed in claim 17 or claim 18, wherein the diameter of wire wound to form the coil

is approximately between 0.025 and 0.125 mm.

20. A combination as claimed in claim 15, wherein the coil of the tip portion (56) defines an interior space, said interior space being free and unreinforced.

21. A combination as claimed in any one of the preceding claims, wherein the distal end of the tip portion (28,56) is provided with a platinum soldered tip (30,58) to form a rounded and smooth termination to avoid puncturing the vascular cavity.

22. A combination as claimed in any one of claims 1 to 4, wherein the core wire is between 50 and 300 cm in length.

23. A combination as claimed in any one of claims 1 to 4, wherein the main body (12,16,32) of the core wire is covered with insulation (24) to prevent the underlying portion of the guidewire from coming into contact with blood.

24. A combination as claimed in any one of claims 15, 16 and 20, wherein the voltage source (70) to which the guidewire is connected is arranged to supply a current of approximately 0.01 to 2 milliamps to the guidewire at 0.1 to 6 volts.

25. A combination as claimed in claim 24, wherein the distal portion (46) of the core wire is such that, when the voltage source (70) is operated with the tip portion (56) disposed in the vascular cavity, electrolytic disintegration of said at least one portion of the distal portion (46) of the core wire takes place within 3 to 10 minutes, preferably about 4 minutes, to detach the tip portion from the main body of the core wire.

26. A combination as claimed in any one of claims 15, 16, 20, 24 and 25, wherein the voltage source (70) includes a negative pole (72) for placement in contact with the skin of the patient having the vascular cavity.

27. A combination as claimed in any one of the preceding claims, wherein the vascular cavity is an aneurysm.

28. A combination as claimed in any one of the preceding claims, further comprising the microcatheter (44), having the guidewire (10,42) disposed therein.

Patentansprüche

1. Kombination eines Führungsdrahts (10, 42) mit einer Spannungsquelle (70), bei der der Führungsdraht (10, 42) mit der Spannungsquelle (70) verbunden ist und zusammen mit einem Mikrokatheter (44) in der endovaskulären Elektrothrombose verwendet wird, und der Führungsdraht (10, 42) aufweist:

einen Kerndraht, der einen Hauptkörper (12, 16; 32) und eine distalen Abschnitt (18, 26; 36, 46) hat; und
einen Spitzenabschnitt (28, 56), der zur endovaskulären Einführung innerhalb eines Blutgefäßes mit dem Hauptkörper (12, 16, 32) über den distalen Abschnitt (18, 26, 36, 46) gekoppelt ist und aus einem Material besteht, welches im Blut nicht elektrolytisch auflösbar ist;
wobei der distale Abschnitt (18, 26, 36, 46) der elektrolytischen Auflösung im Blut unterworfen ist, wodurch bei der Einspeisung von Strom in den Führungsdraht (10, 42) durch die Spannungsquelle, wenn der Spitzenabschnitt (28, 56) in dem Blutgefäß liegt, eine endovaskuläre Elektrothrombose durchgeführt werden kann und wenigstens ein Teil des distalen Abschnitts (18, 26, 36, 46) elektrolytisch aufgelöst wird, um den Spitzenabschnitt (28, 56) vom Hauptkörper (12, 16, 32) zu trennen.

2. Kombination nach Anspruch 1, bei der der distale Abschnitt (18, 26, 36, 46) ein freiliegendes Segment aus rostfreiem Stahl aufweist.

3. Kombination nach Anspruch 2, bei der das Segment aus rostfreiem Stahl eine rostfreie Stahlspule (26, 36, 46) aufweist, die an ihrem proximalen Ende mit dem Kerndraht und an ihrem distalen Ende mit dem Spitzenabschnitt (28, 56) verbunden ist.

4. Kombination nach Anspruch 3, bei der das Segment aus rostfreiem Stahl außerdem eine fadenartige Verlängerung (18, 52) des Hauptkörpers (12, 16) des Kerndrahts aufweist, die sich konzentrisch innerhalb der rostfreien Stahlspule (26, 46) erstreckt und an ihrem distalen Ende mit der Verbindung des distalen Endes der rostfreien Stahlspule (26, 46) mit dem Spitzenabschnitt (28, 56) verbunden ist, wobei sowohl die fadenartige Verlängerung (18, 52) als auch die rostfreie Stahlspule (26, 46) der elektrolytischen Auflösung an wenigstens einem Punkt unterworfen sind, um den Spitzenabschnitt (28, 56) vom Hauptkörper (12, 16) abzutrennen.

5. Kombination nach Anspruch 3, bei der die rostfreie Stahlspule (36) einen Innenraum definiert, der frei und unverstärkt ist.

6. Kombination nach Anspruch 3 oder 4, bei der die rostfreie Stahlspule (26) zwischen 3 cm und 10 cm lang ist und einen Durchmesser zwischen 0,254 mm und 0,508 mm hat.

7. Kombination nach einem der vorangehenden Ansprüche, bei der der Spitzenabschnitt (28, 56) aus einem der elektrolytischen Auflösung im Blut nicht unterworfenen Metall besteht.

8. Kombination nach Anspruch 1, bei der der Spitzenabschnitt (28, 56) aus Platin oder einer Platinlegierung besteht.

9. Kombination nach Anspruch 8, bei der der Spitzenabschnitt (28, 56) aus 479 Platinlegierung besteht.

10. Kombination nach einem der vorangehenden Ansprüche, bei der der Spitzenabschnitt (28, 56) ein langes und biegsames Segment ist.

11. Kombination nach einem der Ansprüche 1-4, bei der der Spitzenabschnitt (28) ein langes und biegsames Segment aufweist und das Segment vorgespannt ist, um eine Schrauben- oder Spiralspule zu bilden, wenn es vom Mikrokatheter in das Blutgefäß vorgeschoben wird.

12. Kombination nach Anspruch 11, bei der die Schrauben- oder Spiralspule zwischen 2 mm und 10 mm Durchmesser hat.

13. Kombination nach Anspruch 11 oder 12, bei der die Schrauben- oder Spiralspule zu einer kegelförmigen Einhüllenden vorgespannt ist.

14. Kombination nach Anspruch 11 oder 12, bei der die Schrauben- oder Spiralspule in Form einer zylindrischen Einhüllenden vorgespannt ist.

15. Kombination nach einem der Ansprüche 1-4, bei der der Spitzenabschnitt (56) eine Spule aufweist, die nicht vorgespannt ist.

16. Kombination nach Anspruch 15, bei der der Spitzenabschnitt (56) eine Länge von annähernd 1 cm bis 50 cm hat.

17. Kombination nach einem der Ansprüche 1-4, bei der der Spitzenabschnitt (28) aus einem der elektrolytischen Auflösung im Blut nicht unterworfenen Metall besteht, ein langes und biegsames Segment ist und eine durch das lange und biegsame Segment gebildete Spule aufweist.

18. Kombination nach Anspruch 17, bei der die Spule einen Durchmesser zwischen 0,254 mm und 0,508 mm hat.

19. Kombination nach Anspruch 17 oder 18, bei der der Durchmesser des zur Spule gewickelten Drahts annähernd zwischen 0,025 mm und 0,125 mm liegt.

20. Kombination nach Anspruch 15, bei der die Spule des Spitzenabschnitts (56) einen Innenraum definiert, welcher frei und unverstärkt ist.

21. Kombination nach einem der vorangehenden Ansprüche, bei der das distale Ende des Spitzenabschnitts (28, 56) mit einer platingelöteten Spitze (28, 58) versehen ist und ein abgerundetes und glattes Ende bildet, um so einen Durchstich des Blutgefäßes zu vermeiden.

22. Kombination nach einem der Ansprüche 1-4, bei der der Kerndraht zwischen 50 cm und 300 cm lang ist.

23. Kombination nach einem der Ansprüche 1-4, bei der der Hauptkörper (12, 16, 32) des Kerndrahts mit einer Isolation (24) umhüllt ist, um den darunter liegenden Abschnitt des Führungdrahts vor einer Berührung mit Blut zu schützen.

24. Kombination nach einem der Ansprüche 15, 16 und 20, bei der die mit dem Führungsdraht verbundene Spannungsquelle (70) so eingerichtet ist, daß sie dem Führungsdraht einen Strom von annähernd 0,01-2 Milliampere bei 0,1-6 Volt einspeist.

25. Kombination nach Anspruch 24, bei der der distale Abschnitt (46) des Kerndrahts so ist, daß, wenn die Spannungsquelle (70) mit dem im Blutgefäß liegenden Spitzenabschnitt (56) betrieben wird, eine elektrolytische Auflösung wenigstens eines Teils des distalen Abschnitts (46) des Kerndrahts innerhalb von 3-10 Minuten, bevorzugt innerhalb etwa 4 Minuten stattfindet, um den Spitzenabschnitt vom Hauptkörper des Kerndrahts abzulösen.

26. Kombination nach einem der Ansprüche 15, 16, 20, 24 und 25, bei der die Spannungsquelle (70) einen negativen Pol (72) enthält, der in Kontakt mit der Haut des Patienten mit dem Blutgefäß bringbar ist.

27. Kombination nach einem der vorangehenden Ansprüche, bei der das Blutgefäß ein Aneurysma ist.

28. Kombination nach einem der vorangehenden Ansprüche die außerdem den Mikrokatheter (44) mit dem darin liegenden Führungsdraht (10, 42) aufweist.

Revendications

1. Combinaison d'un fil de guidage (10, 42) et d'une source de tension (70), le fil de guidage (10, 42) étant connecté à la source de tension (70) et étant destiné à l'utilisation avec un microcathéter (44) dans l'électrothrombose endovasculaire, le fil de

guidage (10, 42) comprenant :

un fil de coeur comportant un corps principal (12, 16 ; 32) et une partie distale (18, 26 ; 36, 46) ; et
une partie de pointe (28, 56) pour l'insertion endovasculaire à l'intérieur d'une cavité vasculaire, ladite partie de pointe étant couplée audit corps principal (12, 16, 32) par l'intermédiaire de ladite partie distale (18, 26, 36, 46) et composée d'un matériau qui n'est pas susceptible de subir une désintégration électrolytique dans le sang ;
dans laquelle ladite partie distale (18, 26, 36, 46) est susceptible de subir une désintégration électrolytique dans le sang, grâce à quoi, lors de l'application d'un courant au fil de guidage (10, 42) par la source de tension lorsque ladite partie de pointe (28, 56) est disposée dans la cavité vasculaire, une électrothrombose endovasculaire peut être effectuée et au moins une partie de ladite partie distale (18, 26, 36, 46) peut être électrolytiquement désintégrée de façon à détacher ladite partie de pointe (28, 56) dudit corps principal (12, 16, 32).

2. Combinaison selon la revendication 1, dans laquelle ladite partie distale (18, 26, 36, 46) comprend un segment en acier inoxydable exposé.

3. Combinaison selon la revendication 2, dans laquelle ledit segment en acier inoxydable comprend un serpentin en acier inoxydable (26, 36, 46) raccordé en son extrémité proximale audit fil de coeur et raccordé en son extrémité distale à ladite partie de pointe (28, 56).

4. Combinaison selon la revendication 3, dans laquelle ledit segment en acier inoxydable comprend de plus un prolongement analogue à un filament (18, 52) du corps principal (12, 16) du fil de coeur, qui s'étend de façon concentrique à l'intérieur dudit serpentin en acier inoxydable (26, 46), et qui est raccordé en son extrémité distale au raccordement de l'extrémité distale du serpentin en acier inoxydable (26, 46) et de la partie de pointe (28, 56), ledit prolongement analogue à un filament (18, 52) et ledit serpentin en acier inoxydable (26, 46) étant tous deux susceptibles de subir une désintégration électrolytique au moins en un point de façon à détacher la partie de pointe (28, 56) du corps principal (12, 16).

5. Combinaison selon la revendication 3, dans laquelle ledit serpentin en acier inoxydable (36) définit un espace intérieur, ledit espace intérieur étant libre et non renforcé.

6. Combinaison selon la revendication 3 ou la revendication 4, dans laquelle le serpentin en acier inoxydable (26) a une longueur comprise entre 3 et 10 cm et a un diamètre compris entre 0,254 mm et 0,508 mm.

7. Combinaison selon l'une quelconque des revendications précédentes, dans laquelle la partie de pointe (28, 56) se compose d'un métal qui n'est pas susceptible de subir une désintégration électrolytique dans le sang.

8. Combinaison selon la revendication 1, dans laquelle la partie de pointe (28, 56) est réalisée en platine ou en alliage de platine.

9. Combinaison selon la revendication 8, dans laquelle la partie de pointe (28, 56) est réalisée en alliage de platine 479.

10. Combinaison selon l'une quelconque des revendications précédentes, dans laquelle la partie de pointe (28, 56) est un segment long et pliable.

11. Combinaison selon l'une quelconque des revendications 1 à 4, dans laquelle la partie de pointe (28) comprend un segment long et pliable, et ledit segment est précontraint de façon à former un serpentin hélicoïdal ou spiral lorsqu'on le fait avancer depuis le microcathéter dans la cavité vasculaire.

12. Combinaison selon la revendication 11, dans laquelle le serpentin hélicoïdal ou spiral a un diamètre compris entre 2 et 10 mm.

13. Combinaison selon la revendication 11 ou la revendication 12, dans laquelle le serpentin hélicoïdal ou spiral est précontraint de façon à avoir une enveloppe conique.

14. Combinaison selon la revendication 11 ou la revendication 12, dans laquelle le serpentin hélicoïdal ou spiral est précontraint de façon à avoir une enveloppe cylindrique.

15. Combinaison selon l'une quelconque des revendications 1 à 4, dans laquelle la partie de pointe (56) comprend un serpentin qui n'est pas précontraint.

16. Combinaison selon la revendication 15, dans laquelle la partie de pointe (56) a une longueur comprise approximativement entre 1 et 50 cm.

17. Combinaison selon l'une quelconque des revendications 1 à 4, dans laquelle la partie de pointe (28) se compose d'un métal qui n'est pas susceptible de subir une désintégration électrolytique dans le sang, est un segment long et pliable, et comporte

un serpentin formé par le segment long et pliable.

18. Combinaison selon la revendication 17, dans laquelle le serpentin a un diamètre compris entre 0,254 et 0,508 mm.

19. Combinaison selon la revendication 17 ou la revendication 18, dans laquelle le diamètre du fil enroulé pour former le serpentin est compris approximativement entre 0,025 et 0,125 mm.

20. Combinaison selon la revendication 15, dans laquelle le serpentin de la partie de pointe (56) définit un espace intérieur, ledit espace intérieur étant libre et non renforcé.

21. Combinaison selon l'une quelconque des revendications précédentes, dans laquelle l'extrémité distale de la partie de pointe (28, 56) comporte une pointe soudée au platine (30, 58) afin de former une terminaison ronde et lisse afin d'éviter de percer la cavité vasculaire.

22. Combinaison selon l'une quelconque des revendications 1 à 4, dans laquelle le fil de coeur a une longueur comprise entre 50 et 300 cm.

23. Combinaison selon l'une quelconque des revendications 1 à 4, dans laquelle le corps principal (12, 16, 32) du fil de coeur est recouvert d'un isolant (24) pour empêcher la partie sous-jacente du fil de guidage de venir en contact avec le sang.

24. Combinaison selon l'une quelconque des revendications 15, 16 et 20, dans laquelle la source de tension (70) à laquelle est connecté le fil de guidage est agencée de façon à délivrer un courant compris approximativement entre 0,01 et 2 milliampères au fil de guidage sous 0,1 à 6 volts.

25. Combinaison selon la revendication 24, dans laquelle la partie distale (46) du fil de coeur est telle que, lorsque la source de tension (70) fonctionne avec la partie de pointe (56) disposée dans la cavité vasculaire, la désintégration électrolytique de ladite partie au nombre d'au moins une de la partie distale (46) du fil de coeur s'effectue en 3 à 10 minutes, et, de préférence, en 4 minutes environ, de façon à détacher la partie de pointe du corps principal du fil de coeur.

26. Combinaison selon l'une quelconque des revendications 15, 16, 20, 24 et 25, dans laquelle la source de tension (70) comprend un pole négatif (72) pour la disposition en contact avec la peau du patient possédant la cavité vasculaire.

27. Combinaison selon l'une quelconque des revendications précédentes, dans laquelle la cavité vasculaire est un anévrisme.

28. Combinaison selon l'une quelconque des revendications précédentes, comprenant de plus le microcathéter (44), dans lequel est disposé le fil de guidage (10, 42).

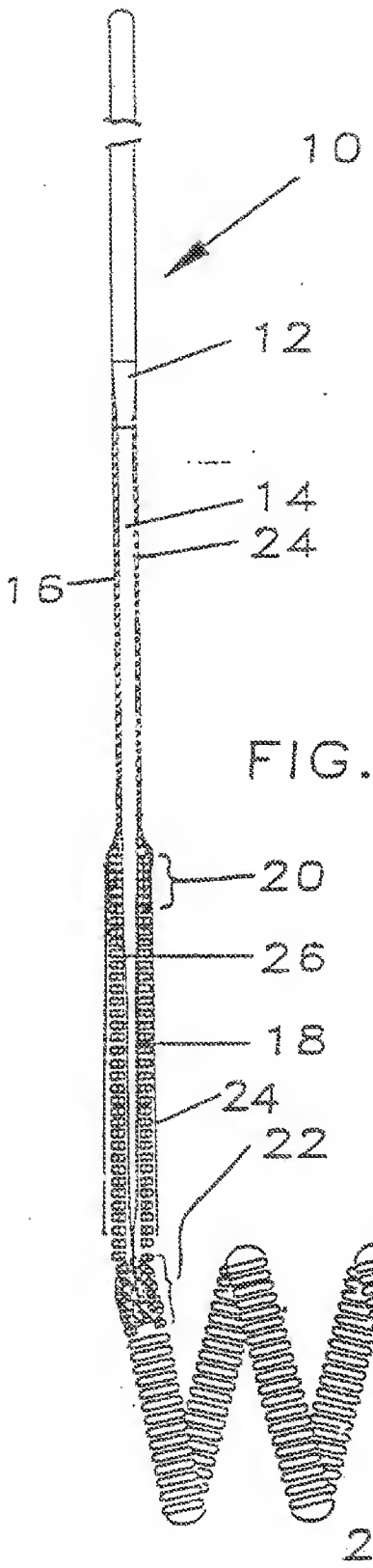


FIG. 1

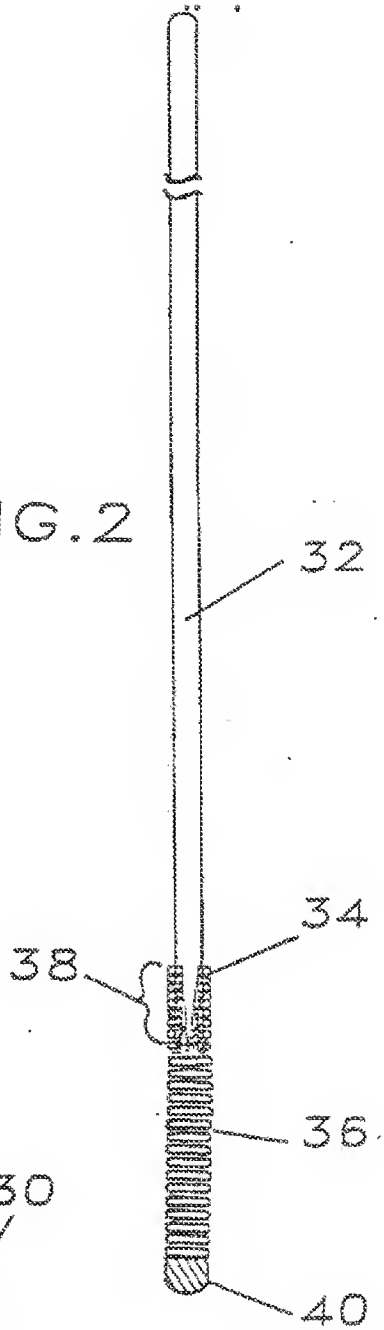


FIG. 2

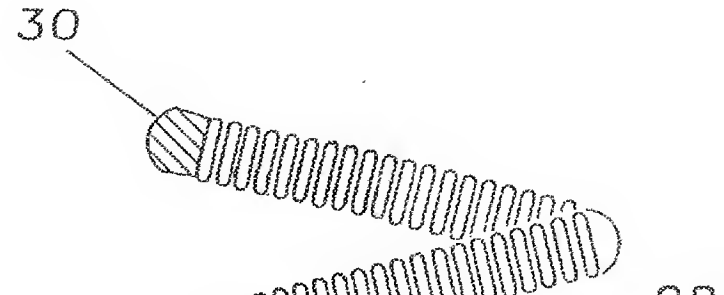


FIG. 1A

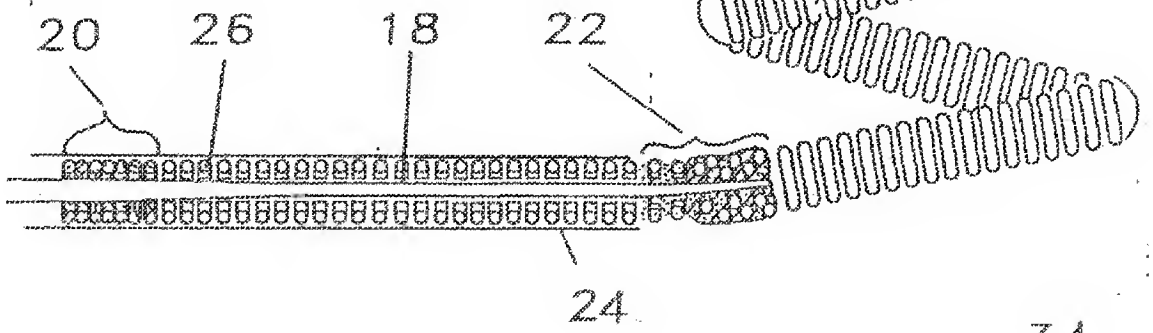
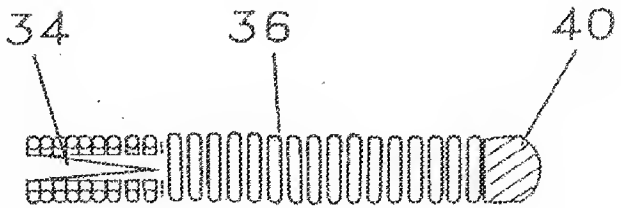


FIG. 2A



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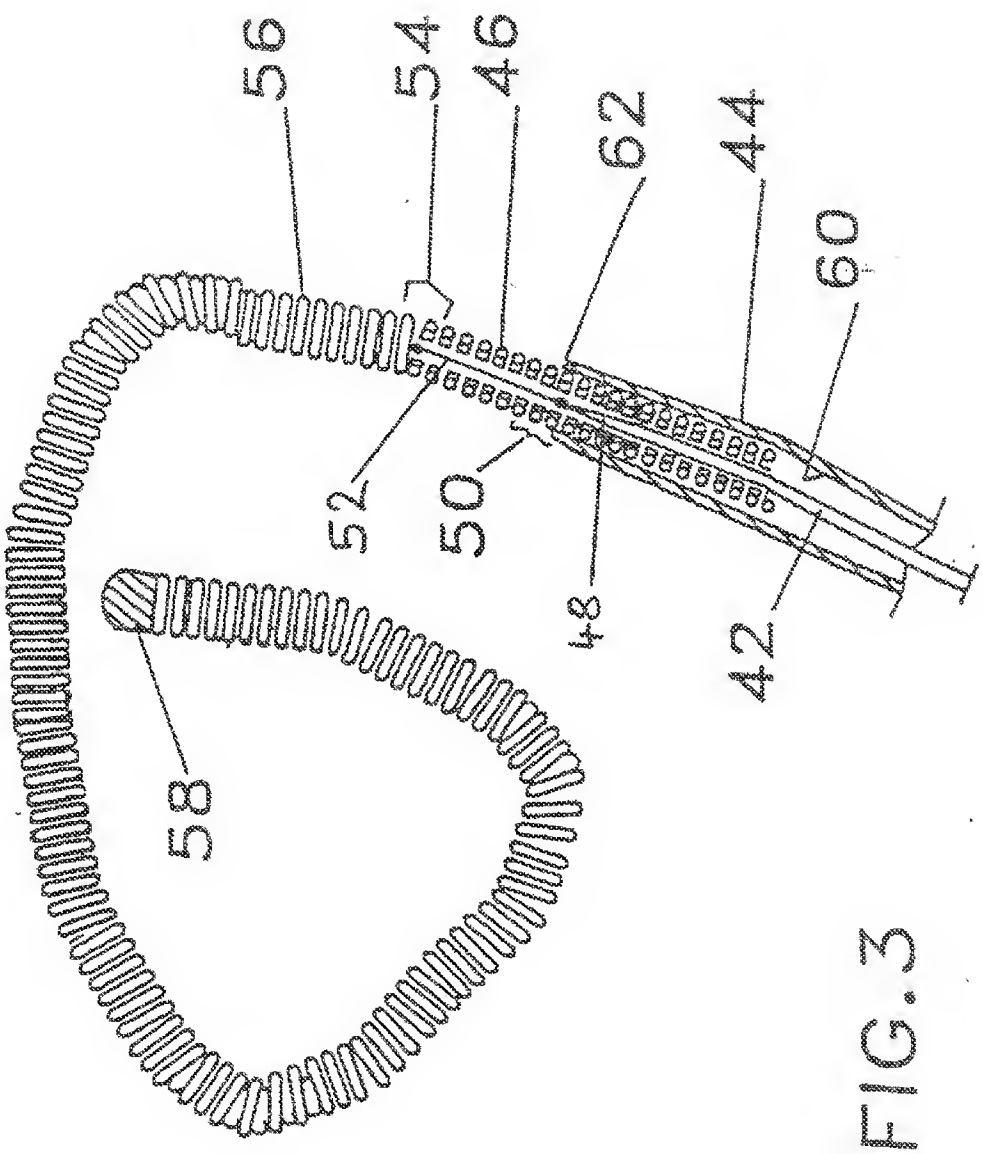

FIG. 3

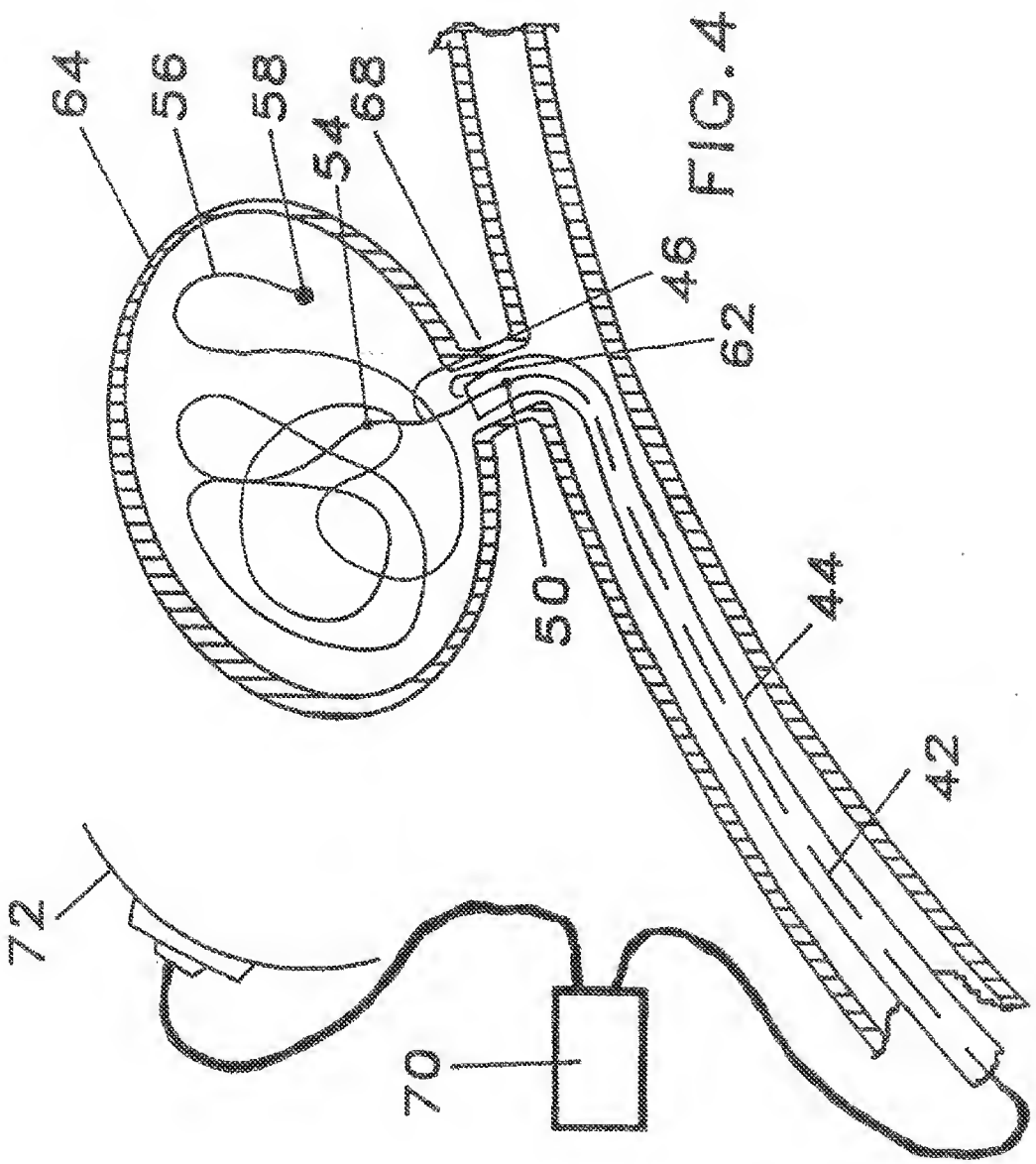

FIG. 4

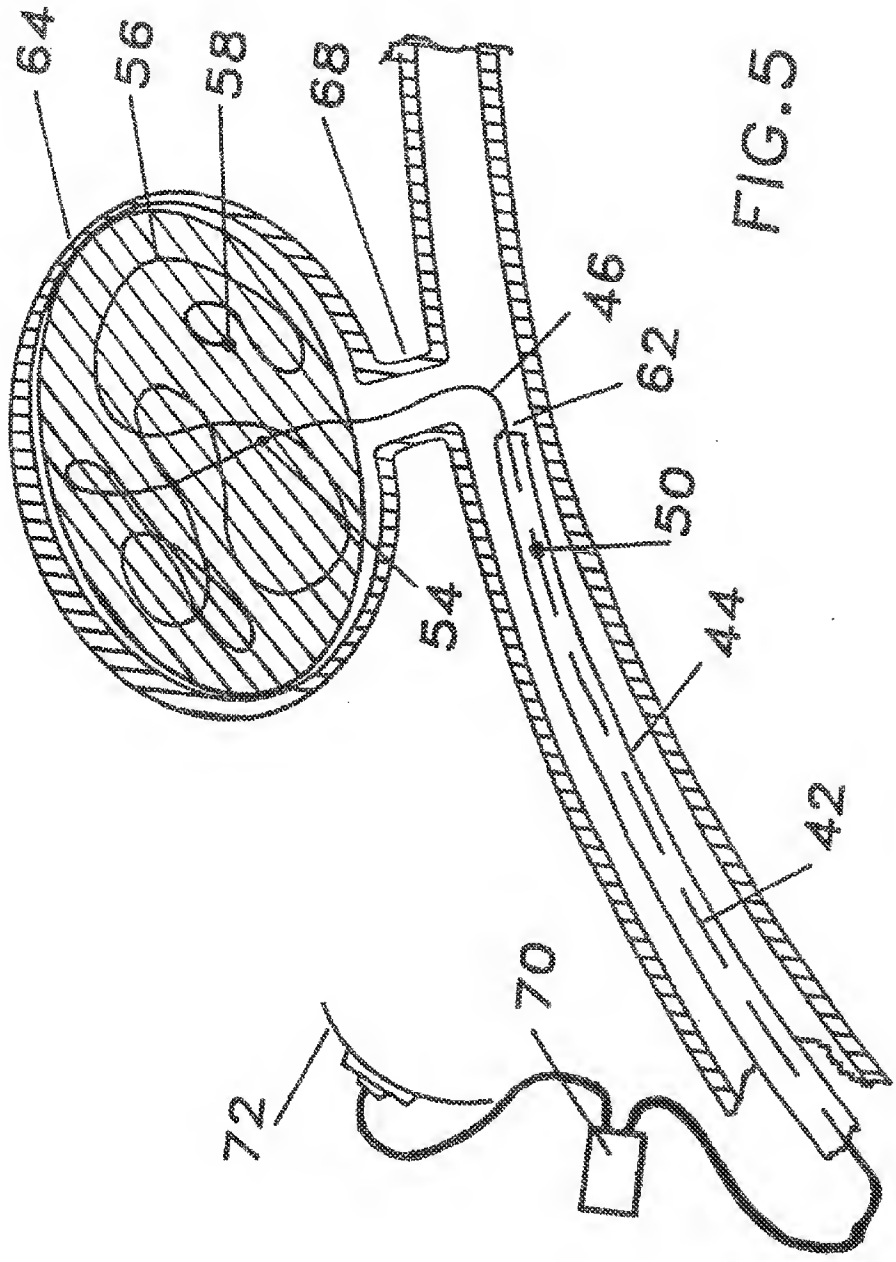

FIG. 5